REMARKS

In the Office Action dated May 7, 2007, claims 16-18, 37 and 41-42 are pending and under consideration. The Examiner has objected to Applicants' claim of priority from Australian Applications PN 1239/95 and PN 5172/95, and has determined that Applicants are entitled only to the filing date of PCT/AU/0085, i.e., February 20, 1996. Claims 16-18, 37 and 41-42 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent 6,509,165.

This Response addresses the Examiner's objection and rejection. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

In the first instance, Applicants direct the Examiner's attention to the amendment to claim 16. Claim 16, as amended, is directed to a method for determining the reactivity of a subject to IDDM autoantigen comprising contacting T-cells derived from the subject with a peptide comprising FFYTPKTRREAED (SEQ ID NO: 1), and measuring the reactivity of the T-cells to the peptide. Support for the recitation, "a peptide comprising FFYTPKTRREAED (SEQ ID NO: 1)", is found throughout the specification, e.g., page 3, lines 12-28. No new matter is introduced by the foregoing amendment.

With respect to Applicant's claim of priority, it is respectfully submitted that support for the presently claimed methods which employ a peptide comprising FFYTPKTRREAED (SEQ ID NO: 1), are also found in both Australian priority documents. Specifically, the amino acid sequence defined in SEQ ID NO: 1 is specifically described at page 2, line 20, page 3, line 3, Example 1 (page 7, line 12) and Figure 1. Example 1 on page 7 of PN1239/95 clearly states that one of the peptides actually synthesized was proinsulin amino acid 24-36 (i.e., SEQ ID NO: 1). This priority document further states that the synthesized peptides of the present

invention were determined to be immunointeractive based on interactivity of T-cells from subjects suffering from IDDM (see page 2, lines 10 to 13). Additionally, on page 5, lines 6-15 of PN1239/95, it is stated that the invention contemplates the use of the synthetic peptide to measure reactivity of a subject's cells to the IDDM autoantigen; and further at lines 20-28 of page 5 and in Example 1, the specification of PN1239/95 describes measuring the reactivity of a subject's T-cells to the IDDM autoantigen by using a synthetic peptide, including the proinsulin peptide (SEQ ID NO: 1). Therefore, it is respectfully submitted that the presently claimed methods are entitled to the benefit of the filing date of PN1239/95, i.e., February 20, 1995.

Furthermore, all relevant aspects relating to the presently claimed methods disclosed in PN1239/95 are also disclosed in PN5172/95. PN5172/95 includes additional data showing that T-cell responses to the proinsulin (24-36) peptide (SEQ ID NO: 1) were higher in IDDM at risk subjects than a controlled subject. Thus, it is respectfully submitted that the presently claimed methods are also entitled to the benefit of the filing date of PN5172/95, i.e., September 7, 1995.

In view of the foregoing, withdrawal of the objection to Applicants' claim of priority to PN1239/95 and PN5172/95 is respectfully requested.

Turning to the rejection under 35 U.S.C. §102(e) based on U.S. Patent 6,509,165, the Examiner alleges that the '165 patent teaches a method of contacting T cells isolated from blood with SEQ ID NO: 1 (SEQ ID NO: 4 in the '165 patent), and measuring T cell reactivity by employing a proliferation assay.

In the first instance, Applicants observe that contrary to the Examiner's allegation, the '165 patent does not teach a method of contacting T cells with a peptide having a sequence

identical with instant SEQ ID NO: 1. It is observed that SEQ ID NO: 4 of the '165 patent is longer than instant SEQ ID NO: 1.

Furthermore, Applicants observe that the '165 patent issued from Serial No. 08/472,704, filed on June 6, 1995, which is a continuation-in-part of Serial No. 08/272,220, filed on July 8, 1994. Applicants respectfully submit that the disclosure of the '165 patent relating to a method that employs SEQ ID NO: 4, is not found in Serial No. 08/272,220, and is therefore not entitled to the filing date (July 8, 1994) of Serial No. 08/272,220.

More specifically, Serial No. 08/272,220 does not disclose any peptide having the sequence as set forth in SEQ ID NO: 4 of the '165 patent, or SEQ ID NO: 1 of the present application. Serial No. 08/272,220 only discloses synthetic peptides derived from rat proinsulin, which are distinct from the human proinsulin peptide of SEQ ID NO: 1 of the present application.

Moreover, Serial No. 08/272,220 does not disclose anywhere the use of any synthetic peptide, much less a peptide having the sequence of instant SEQ ID NO: 1, for determining the reactivity of a subject to IDDM autoantigen as presently claimed. Serial No. 08/272,220 is directed to the use of the invariant chain peptide associated with MHC class II molecules or certain of its sequences to interfere with the presentation of (auto) antigenic peptides derived from other proteins. Each of the Examples in Serial No. 08/272,220 purports to demonstrate the possibility of predicting pathogenic T-cell epitopes by using a pre-determined MHC-binding motif. Example 2 demonstrates the prediction of sequences of rat proinsulins 1 and 2, which serve as pathogenic T-cell epitopes in a rat experimental system. It is stated in Example 2 of Serial No. 08/272,220, that "[t]his example further provides a novel, antigen-specific model of autoimmune insulitis...", but the application does not teach or

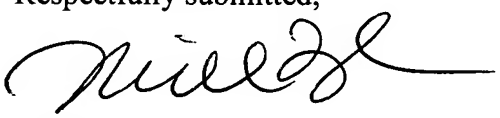
suggest the use of the proinsulin peptides, from rat or otherwise, for diagnosis of autoimmune diseases, or for measuring the reactivity of a subject to IDDM autoantigen as presently claimed.

Accordingly, Applicants respectfully submit that the disclosure of the '165 patent relating to a method which involves contacting T cells with SEQ ID NO: 4, is not supported by Serial No. 08/272,220, and thus not entitled to the filing date (July 8, 1994) of Serial No. 08/272,220, and is only entitled to the filing date (June 6, 1995) of Serial No. 08/472,704. Because the presently claimed methods are entitled to the priority date of PN1239/95, i.e., February 20, 1995, as submitted above, the '165 patent is not *prior* art against the claimed methods.

Therefore, the rejection under 35 U.S.C. §102(e) based on the '165 patent is overcome. Withdrawal of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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